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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/650,783	05/20/96	SCHMITT	P 498-53-CON

HOFFMANN AND BARON
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33M1/0829

CUDDY, J. P. EXAMINER	
ART UNIT	PAPER NUMBER
3308	

DATE MAILED:

08/29/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/650,783

Applicant(s)

SCHMITT, P.J. ET AL.

Examiner

Francis K. Cuddihy

Group Art Unit

3308



☒ Responsive to communication(s) filed on May 20, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on May 20, 1996 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Drawings

1. The drawings are objected to because Figure 1 is not designated by a legend such as "Prior Art". The legend is necessary in order to clarify what applicant's invention is. MPEP 608.02(g). Correction is required.

35 U.S.C. 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention.

Applicant fails to adequately define what is meant by "peak to peak amplitude."

Throughout the specification, applicant points out the criticality of peak-to-peak amplitude. However, there appears to be a discrepancy as to what the maximum peak-to-peak amplitude must actually be. On page 3, lines 30-31, applicant recites a peak-to-peak amplitude not in excess of 0.5 mm, while on page 7, lines 22-24, applicant discloses a peak-to-peak amplitude of no greater than 0.6 mm. This discrepancy is a source of confusion

insofar as the criticality of peak-to-peak amplitude is concerned.

4. Claims 4, 7, 8, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

5. Claims 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 includes a double recitation of elements; that is, "a plurality of wave-like crimps" (page 11, lines 9 and 10).

Claim 13 is rejected as being of improper dependent form for failing to further limit the subject matter of a previous claim. That is, claim 13, like claim 11, recites "... a crimp... of no less than 8 crimps per centimeter" (page 11, lines 16 and 17).

With respect to claims 11 and 16, the recitation of "may be" is indefinite for failing to positively claim the limitation.

The claims will be treated as best as they can given applicant's failure to adequately define what is meant by "peak to peak amplitude."

35 U.S.C. 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeckel (3,105,492).

With respect to claim 11, Jeckel discloses a tubular graft having the number of crimps per centimeter within the range as claimed by applicant (column 4, lines 47-54).

With respect to claim 16, the Jeckel device is clearly capable of being compressed for insertion into an endoluminal catheter. Furthermore, applicant's claim does not require this limitation.

35 U.S.C. 103

8. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Claims 1, 5, 6, and 10 are rejected under 35 U.S.C. 103 as being unpatentable over Wesolowski (3,588,920) in view of Jeckel.

With respect to claims 1, 5, and 6, Wesolowski discloses a crimped fabric implant in tubular form having a wall thickness within the range as claimed by applicant (column 2, lines 35-39). However, Wesolowski does not disclose a frequency of crimps per centimeter.

Jeckel teaches a woven graft having the number of crimps per centimeter within the range as claimed by applicant (column 4, lines 47-54) in order to prevent collapse and kinking (column 1, lines 57-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the number of crimps per centimeter, as taught by Jeckel, in the design of Wesolowski, in order to prevent collapse and kinking of the implant.

With respect to claim 10, Wesolowski discloses a woven implant in bifurcated form (figure 2). Therefore, it would have been an obvious matter of design choice for applicant to have used a bifurcated graft as disclosed by Wesolowski, based upon where in the body the graft was to have been placed.

10. Claims 2, 3, 8, and 9 are rejected under 35 U.S.C. 103 as being unpatentable over Wesolowski in view of Jeckel in further view of Arpesani (WO 88/06026).

With respect to claims 2, 3, 8, and 9, Wesolowski, as modified by Jeckel, discloses a crimped tubular fabric implant. However, neither Wesolowski nor Jeckel disclose an implant including an x-ray detectible radiopaque yarn.

Arpesani teaches a tubular prosthesis having a radiopaque portion defined by a longitudinal filiform element serving to aid in proper positioning of the prosthesis (figures 1 and 2, element 5a).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the radiopaque longitudinal filiform element, as taught by Arpesani, in the design of the modified Wesolowski, in order to ensure the proper positioning of the implant within the body.

11. Claims 4 and 7, as best understood, are rejected under 35 U.S.C. 103 as being unpatentable over Wesolowski in view of Jeckel as applied to claims 1 and 6 above, and further in view of

Seiler, Jr., et al. (4,550,447). Neither Wesolowski nor Jeckel disclose applicant's peak-to-peak amplitude.

With respect to claims 4 and 7, Seiler teaches a ribbed vascular graft prosthesis wherein the rib rise (herein interpreted as applicant's peak-to-peak amplitude) is within the range as claimed by applicant (column 4, lines 20-22), and serves to inhibit tube collapse due to kinking when the tube is bent (column 1, lines 56-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the rib rise, as taught by Seiler, in the modified design of Wesolowski, in order to prevent tube collapse due to kinking when the tube is bent.

12. Claims 12 and 13 are rejected under 35 U.S.C. 103 as being unpatentable over Jeckel in view of Wesolowski.

With respect to claims 12 and 13, Jeckel discloses a woven graft having the number of crimps per centimeter within the range as claimed by applicant (column 4, lines 47-54). However, Jeckel does not disclose a wall thickness.

Wesolowski teaches an implant having a wall thickness within the range as claimed by applicant (column 2, lines 35-39) which represents an appreciable advance in terms of flexibility and porosity (column 1, lines 50-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated

the wall thickness as taught by Wesolowski in the design of Jeckel in order to enhance the flexibility and porosity of the graft.

13. Claim 14 is rejected under 35 U.S.C. 103 as being unpatentable over Jeckel in view of Wesolowski as applied to claims 11, 12, and 13 above, and further in view of Seiler.

Neither Jeckel nor Wesolowski disclose applicant's peak-to-peak amplitude.

With respect to claim 14, Seiler teaches a ribbed vascular graft prosthesis wherein the rib rise (applicant's peak-to-peak amplitude) is within the range as claimed by applicant (column 4, lines 20-22), and serves to inhibit tube collapse due to kinking when the tube is bent (column 1, lines 56-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the rib rise, as taught by Seiler, in the modified design of Jeckel, in order to prevent tube collapse due to kinking when the tube is bent.

14. Claim 15 is rejected under 35 U.S.C. 103 as being unpatentable over Jeckel in view of Wesolowski in further view of Arpesani.

Jeckel, as modified by Wesolowski, discloses a crimped tubular fabric implant. However, neither Wesolowski nor Jeckel disclose an implant including an x-ray detectable radiopaque yarn.

Arpesani teaches a tubular prosthesis having a radiopaque portion defined by a longitudinal filiform element serving to aid in proper positioning of the prosthesis (figures 1 and 2, element 5a).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have incorporated the radiopaque longitudinal filiform element as taught by Arpesani in the design of the modified Jeckel in order to ensure proper positioning of the implant within the body.

15. Claim 17 is rejected under 35 U.S.C. 103 as being unpatentable over Jeckel in view of Wesolowski.

Jeckel discloses a tubular graft having the number of crimps per centimeter within the range as claimed by applicant (column 4, lines 47-54). However, Jeckel does not disclose a bifurcated graft.

Bifurcated grafts are well known in the art as shown by Wesolowski, who teaches both bifurcated and unbifurcated embodiments of his implant (figure 2).

Therefore, it would have been an obvious matter of design choice for applicant to have used a bifurcated graft as taught by Wesolowski, based upon where in the body the graft was to have been placed.

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Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hood (4,545,082) and Hood (WO 8303347) disclose corrugated vascular prostheses. Jones (4,202,349) discloses radiopaque vessel markers.

17. Any questions concerning this communication should be directed to Francis K. Cuddihy at telephone number (703)-308-2996. In the event that Applicant/Representative is unable to reach Mr. Cuddihy directly or by voice mail, Applicant may contact Supervisory Patent Examiner Mr. John Weiss at telephone number (703)-308-2702.

For those questions of a general nature, the Group 3300 Receptionist may be reached at telephone number (703)-308-0858.

Additionally, formal facsimile communications should be directed to the Group 3300 Main Fax number (703)-305-3590; informal facsimile communications should be directed to the Art Unit 3308 Fax number (703)-308-0131. Kindly place my name, art unit, and application serial number on the facsimile cover sheet.

Francis K. Cuddihy *FKC*
Assistant Examiner
August 27, 1996


JOHN G. WEISS
SUPERVISORY PATENT EXAMINER
GROUP 3300